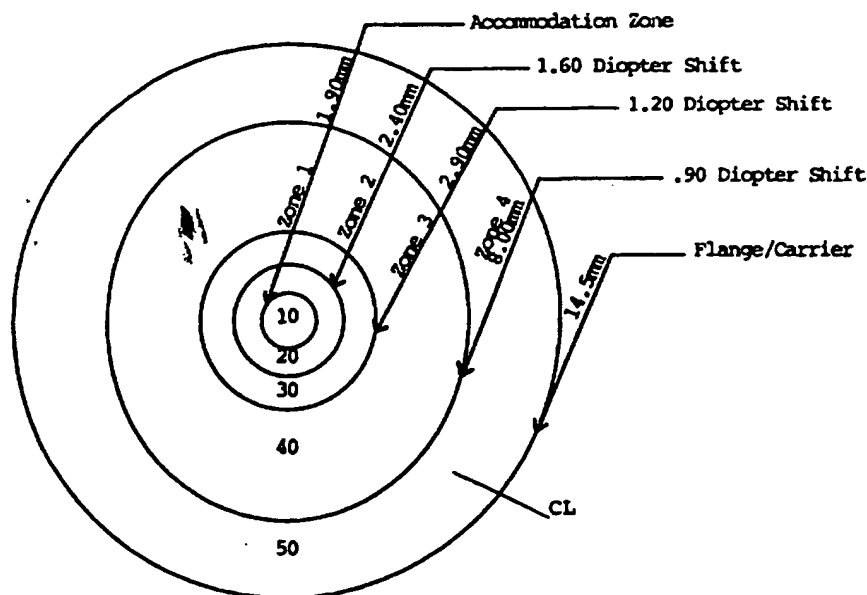




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(54) Title: CONTACT LENS AND PROCESS FOR FITTING



(57) Abstract

A contact lens with a central region (10) that is optimally less than approximately 1.9 millimeters in diameter and that is preferably overcorrected by approximately 25 % to 100 % over the correction needed for reading. Unexpectedly, the central region (10) does not impair distance vision, but compensates for presbyopia and therefore allows a user to focus on objects within a range of near and intermediate distances. A method for fitting the contact lens is also provided.

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DESCRIPTIONContact Lens and Process for Fitting
Technical Field.

5 This invention relates to a contact lens that restores the ability to focus on objects within a range of distances near to the user (referred to as "natural accommodation"), while retaining the ability to see distant objects. More specifically, this invention
10 relates to a contact lens with a conventional spherical concave surface conforming to the curvature of the eye (base curve) and having a non-conventional convex surface (optic curve) combining spherical and non constant aspherical curvature resulting in an optical
15 system that provides true monocular presbyopic correction (correction of presbyopia in each eye independently, instead of partial or full distance correction in one eye and partial or full near correction in the other) and restores the phenomenon of
20 "natural accommodation." Additionally, the invention affords a methodology of fitting that substantially reduces the skill and experience required by the contact lens fitter to a very basic level while affording a high degree of clinical success and patient satisfaction.

25 Normally between the ages of 40 and 45, presbyopia or old sightlessness is brought about by loss of elasticity of the crystalline lens of the eye, causing blurred vision at near points due to the reduction of the ability of the eye's natural lens to
30 accommodate the changes in curvature necessary to focus on both near and distant objects.

 When a person is free of presbyopia, the eye retains its full range of natural accommodation. This type of person's vision can be corrected by eyeglasses
35 or contact lenses providing only the correction required for distance vision, and natural accommodation would automatically provide correction for near and

1 intermediate distance vision.

Background Art.

For the contact lens wearer who requires presbyopic (or near vision) correction, in addition to
5 distance correction, a variety of options have been available. These individuals may be fitted with single vision contact lenses corrected for distance, and wear reading glasses for near correction. Another
10 alternative is to provide a contact lens for one eye that is corrected for distance vision and to provide a contact lens for the other eye that is corrected for near vision (this practice is referred to as monovision because only one eye is corrected for near vision), or the fitting of bifocal or multifocal contact lenses.

15 During the 1950's, a variety of contact lenses were designed for the correction of presbyopia. These contact lenses, although very innovative in design, met with only limited success because the only readily available material was Poly Methyl Methacrylate
20 (Plexiglass), also known as PMMA, which does not transmit oxygen. As bifocal and multifocal designs of the period were quite thick and heavy compared to conventional distance correction contact lenses, these presbyopic contact lenses were uncomfortable to wear for
25 substantial periods of time. Additionally, the fitting of these bifocal and multifocal contact lenses required considerable time and skill on the part of the contact lens fitter.

During the 1970's, both soft contact lenses and
30 rigid gas permeable (RGP) contact lenses were introduced. With the availability of these new materials, renewed enthusiasm brought about several new designs for contact lenses for the correction of presbyopia.

35 RGP materials provide oxygen transmission through the lens material itself, and afforded new hope for the earlier designs developed in PMMA material.

1 However, lens thickness and resultant patient discomfort continued to be a problem.

One of the early benefits recognized with soft contact lenses was the comfort and ease of fitting and, for this reason, by 1995 approximately 85% of new contact lens wearers are being fitted with soft contact lenses. As soft contact lenses command such a large share of the contact lens market, it is natural that considerable effort would be made to develop bifocal and multifocal contact lens designs in soft contact lens material.

There are two types of contact lens designs for the correction of presbyopia -- Alternating (or Translating) and Simultaneous.

15 (1) In the alternating (or translating) vision technique, the lenses are very similar in design to bifocal eyeglass lenses in that the wearer sees through the distance segment in the upper portion of the lens when looking straight ahead and sees through a lower near vision segment when the eye (moves) to look down. Alternating vision lenses have proven to be successful in RGP designs, but have met with little success when designed in soft contact lenses.

Perhaps the reason that alternating vision soft contact lens designs were not as successful as the same design concept in RGP materials was because lens translation is necessary for this design to be successful. The translation from distance to near is achieved through the mechanical action of the lens resting on the lower eyelid and, when the eye looks down, the lens remains stable on the lower eyelid causing the pupil of the eye to translate from the distant vision portion of the lens to the near vision portion of the lens. Soft lens material by its nature caused this modality to fail as there was insufficient rigidity in the soft lens to remain properly positioned

1 on the lower eyelid and often the lens would slip
underneath the lower eyelid during translation.

(2) Simultaneous vision bifocal or multifocal
contact lenses are either concentric or aspheric in
5 design with focal power changing through different areas
of the lens. Lenses are fitted so that distance,
intermediate and near zones focus images simultaneously
on the retina of the eye and the brain then separates
out the image desired.

10 Theoretically, with adaptation, the ability to
change focus naturally from near to far with no blurring
in between can be achieved with simultaneous vision
lenses in both RGP and soft contact lenses.

As alternating presbyopic designs proved to be
15 unsuccessful in soft contact lens designs, most of the
development work with soft contact lenses was done in
the area of simultaneous presbyopic correction with
concentric designs or aspheric designs.

During the 1980's, several designs of
20 concentric and aspheric soft contact lenses were
introduced. Soft aspheric multifocal contact lenses
typically provided relatively weak reading addition
power and therefore worked best in early presbyopia.

Reading addition powers are referred to by eye
25 care professionals as "add" power, and represent the
difference between the distance correction and near
correction prescribed by an eye care professional for
eyeglasses or contact lenses. Accordingly, a
prescription of "-3 with a +2 add" (which would be
30 typical for moderate presbyopia) would mean that
distance vision requires -3 diopters of correction, and
near vision requires an additional 2 diopters of plus
correction, resulting in -1 diopters of near vision
correction. In conventional monovision, the dominant
35 eye would be fitted with a -3 distance correction lens,
and the other eye would be fitted with a -1 near
correction lens.

1 This type of solution is often satisfactory in
early presbyopia because the user still has some
remaining visual accommodation and the needed add power
is usually between +.75 and +1.25, which is usually low
5 enough for the brain to comfortably select the desired
image in most people. However, conventional monovision
becomes less satisfactory as presbyopia becomes more
advanced because the needed add power increases and
visual accommodation has deteriorated further, so that
10 the visual imbalance exceeds the brain's ability to
select the desired image from the appropriate eye.

Typically, early presbyopes, would be between
the age of 40 and 45, and would require add power of
between +1.00 and +1.50 diopters. Moderate presbyopes
15 would usually be between 45 and 55 years and would
require add power of between +1.50 and +2.00 diopters.
Mature presbyopes would usually be older than age 55 and
require an add power of between +2.00 and +3.00 diopter.

The add corrective power of current aspheric
20 multifocal contact lens designs is usually limited to
only +.75 to +1.25 diopters because the brain must be
able to separate out the desired image (and also
suppress the undesired images) from the multiple images
(near, intermediate or distant) being simultaneously
25 focused by the multifocal contact lens design. In order
to achieve this suppression, the images cannot be too
different from each other. However, if aspheric
corrections are increased in attempts to achieve higher
add powers, the images become too different for the
30 brain to suppress the undesired images, resulting in
blurred vision. Even at add powers of +.75 to +1.25
diopters, many patients suffer some blurring or ghosting
with multifocal contact lens designs because their
brains are not able to completely separate the desired
35 image while simultaneously completely suppressing the
undesired images.

1 Some contact lens fitters may attempt to use
aspheric designs to achieve near distance correction of
up to +2.00 diopters (or more) by undercorrecting the
distance vision of the non-dominant eye by between .25
5 and 1.00 diopters, thereby theoretically providing up to
+2.00 diopters (or more) of near vision correction,
instead of the +.75 to +1.25 diopter correction that
would be provided if that eye had been fully corrected
for distance vision with an aspheric multifocal contact
10 lens. The dominant eye would be corrected to maximum
distance acuity in such a situation. However, this
creates even more blurring and ghosting. This technique
is called modified monovision.

Aspheric optics have been incorporated on both
15 the front and back surfaces of soft contact lenses.
However, it is believed that front surface aspherical
multifocal soft contact lenses provide better presbyopic
correction. Still, only limited success is achieved
because providing add power of +.75 to +1.25 (or more)
20 usually results in reduced distance acuity. For this
reason, many contact lens fitters find it necessary,
when using aspheric soft multifocal contact lenses, to
undercorrect the distance power in one eye to improve
near vision, while correcting the other eye fully for
25 distance vision, as discussed above. When attempting to
fit moderate to mature presbyopes, this modified
monovision almost always results in a visual compromise
similar to that of conventional monovision.

Concentric multifocal lens designs have an
30 advantage over aspheric designs in the fitting and
correcting of more mature presbyopes requiring add power
of more than +1.25 diopters, primarily due to the
availability of higher add power correction and central
power zones of different diameters. Concentric soft
35 multifocal contact lenses have been made with the
central distant correction zones and central near
correction zones. In the latter designs, the central

1 power zones would be corrected by the amount prescribed
to correct near vision. It is believed that central
near add zones have been more successful at correcting
presbyopia than central distance zones, when
5 incorporated in concentric multifocal soft lens designs.
Although concentric center add multifocal designs have
the ability to correct higher add power requirements,
most individuals fitted with this type of lens
experience moderate to significant amounts of visual
10 discomfort due to ghosting of images or a 3-D effect, at
near distances. These effects diminish with adaptation,
but still cause a high portion of wearers to discontinue
the use of this type of presbyopic contact lens.

The reality of the existing art of presbyopic
15 correction with simultaneous vision contact lenses is
that no currently available lens system, be it aspheric
or concentric, provides monocular multifocal correction
for moderate to mature presbyopia. In most cases, some
form of modified monovision is required in an attempt to
20 satisfy the visual requirement for near and far vision.
To this end almost all currently available presbyopic
contact lens manufacturers indicate in their fitting
manuals the requirement of compensating one eye more for
near and the other eye more for distance correction.
25 This is the norm rather than the exception.
Additionally, no currently available multifocal contact
lens has the ability to restore the phenomena of natural
accommodation and successful results are difficult to
achieve and require considerable time and experience on
30 the part of the fitter.

It is therefore an object of this invention to
provide true multifocal correction for moderate and
mature presbyopes requiring up to +3.00 diopters of add
power without the need to compensate one eye for near
35 and the other eye for distance.

1 It is a further object of this invention to
provide rapid patient adaptation with minimal initial
visual discomfort.

 It is a still further object of this invention
5 to provide a presbyopic optical system that restores the
phenomenon of natural accommodation.

 It is a still further object of this invention
to provide a system of fitting and methodology that
allows a contact lens fitter with little or no
10 multifocal contact lens fitting experience to achieve a
very high degree of success and patient satisfaction.

Disclosure of Invention

 These and other objects are achieved by a
contact lens having a central circular region (an
15 "accommodation zone" or "sweet spot" named zone 1) that
is overcorrected for near vision, and that is small
enough that it does not impair distance vision.
Preferably, a plurality of concentric transition regions
(or rings), optimally two (named zone 2 and zone 3,
20 progressing radially outwardly), are provided between
the sweet spot and the outer region (or ring) of the
lens (named zone 4), which is corrected for distance
vision. Preferably, the sweet spot has a diameter of
between approximately 1.0 millimeters and approximately
25 2.5 millimeters, preferably between approximately 1.5
millimeters and approximately 1.9 millimeters, and
optimally either approximately 1.5 millimeters or
approximately 1.9 millimeters. Preferably, the
transition rings (zones 2 and 3) are each approximately
30 .5 millimeters wide. Preferably also, the remaining
portion of the lens (zone 4) extends radially outward
from the outermost transition ring to at least
approximately 8 millimeters. Because the human pupil
cannot expand beyond approximately 8 millimeters in
35 diameter, the portion of the lens extending more than
approximately 8 millimeters radially outward from the

1 center is not an optical portion and functions only as a carrier.

Preferably, the sweet spot is spherical and is overcorrected by between 25% and 100% over the near vision correction prescribed for the user. Preferably, the remaining optical portions of the lens are aspheric, with different diopter shifts over different regions. Optimally, for high add power, zone 2 provides a diopter shift of approximately 1.6 diopters, zone 3 provides a diopter shift of approximately 1.2 diopters, and zone 4 provides a diopter shift of approximately .9 diopters. For low add power, optimally zone 2 provides a diopter shift of approximately 1.1 diopters, zone 3 provides a diopter shift of approximately .8 diopters, and zone 4 provides a diopter shift of approximately .6 diopters.

The contact lens manufacturing lathe disclosed in the example below provided contact lenses that achieved the desired results. However, some experimentation may be necessary to achieve the desired result with different equipment, but this experimentation should not be undue.

The invention incorporates both concentric and aspheric design principles and can be produced with a high add power correction or a low add power correction. In addition, the lens system offers two accommodation zone diameters for different sized pupils to achieve maximum near point acuity without reduction in distance visual acuity.

The higher add power lens has a power transition of 3.7 diopters across the usable optic zone, and the low add power lens has a power transition of 2.6 diopters across the usable optic zone.

The accommodation zone should cover approximately 50% of the pupil area for maximum success in distant, intermediate and near visual acuity. The accommodation zone functions to restore the phenomenon of natural accommodation by creating a very small area

1 of over magnification in the center of the pupil of
approximately 25% to 100% over the near vision
correction required by the indicated reading add power.
Surprisingly, distance vision will not be substantially
5 impaired if the accommodation zone covers 50% or less of
the pupil area. Further, the function of natural
accommodation will be restored to an unexpectedly great
extent.

Although the inventor is not sure (and the
10 validity and enforceability of any patent issuing hereon
shall not be affected by the accuracy or inaccuracy of
this explanation), the inventor believes that, in near
vision, a user's pupils constrict, so that the
accommodation zone occupies a large enough portion of
15 the pupil area for the accommodation zone to become
effective. Normal reading correction is prescribed for
approximately 15 inches (approximately 38 centimeters).
Accordingly, the overcorrection of the accommodation
zone (sweet spot) allows the user to see from 8 inches
20 to 15 inches, thus restoring the function of natural
accommodation. In distance vision, however, the pupil
will be normally dilated, so that the accommodation zone
is small enough that the brain ignores the image
generated by it. The constriction of the pupil for near
25 vision is known as "accommodative pupil response."

The accommodation zone is blended to the
distance zone 4 via two zones of non constant
aspherocity which allows true monocular correction of
near, intermediate and distant vision. Near vision
30 correction, when tested at the standard distance of
approximately 15 inches (approximately 38 centimeters)
offers normal best corrected acuity and when reading
material is brought closer to the eyes, up to about
eight inches (approximately 20 centimeters), near acuity
35 remains stable and often improves due to the increased
near power created by the sweet spot.

1 Due to the non constant aspheric transition
from the sweet spot to zone 4, adaptation problems
associated with prior designs of concentric or aspheric
multifocal contact lenses are substantially reduced or
5 eliminated completely.

 Historically, the fitting of multifocal contact
lenses has been more an art than a science as the
variables associated with fitting presbyopic contact
lenses are considerable. Often success has only been
10 achieved through the process of trying many different
lenses on the patient in the hope of finding a lens that
generates a good presbyopic response. The contact lens
fitter's degree of experience in the fitting of
multifocal lenses has also been a key to achieving a
15 successful fitting with good visual results.

 The fitting of lenses according to this
invention requires accurate centering of the lens over
the pupil of the eye in order to achieve the expected
results. To determine the location of the sweet spot
20 relative to the pupil is often difficult because the
pupil may not be aligned with the center of the cornea
or for other reasons. Thus, the invention also
incorporates the use of a diagnostic trial lens with a
white ring corresponding in diameter and location to the
25 sweet spot. The exact position of the center of the
contact lens can be determined and the relative position
of the sweet spot to the pupil and the percentage of
pupil covered by the sweet spot is easily observed. The
use of the diagnostic lens allows the fitter to very
30 quickly determine the proper sweet spot size, which
increases the chances of successful fitting. For
example, if the accommodation zone does not align within
the pupil, the fitter knows that the standard lens
design will not work and a custom lens design with an
35 offset accommodation zone will be required.

 Other objects, features and advantages of the
present invention will become more fully apparent from

1 the following detailed description of the presently preferred embodiments for carrying out the invention and the accompanying drawings.

Brief Description of Drawings.

5 Fig. 1 is a top elevational schematic view of a presently preferred embodiment of a contact lens according to the present invention for a person who needs a high degree of reading correction (high add power) and a larger sweet spot;

10 Fig. 2 is a top elevational schematic view of a presently preferred embodiment of a contact lens according to the present invention for a person who needs a high degree of reading correction (high add power) but a smaller sweet spot;

15 Fig. 3 is a top elevational view of a contact lens according to the present invention for a person who needs a lesser degree of reading correction (low add power) and a larger sweet spot; and

20 Fig. 4 is a top elevational view of a contact lens according to the present invention for a person who needs a lesser degree of reading correction (low add power) and a smaller sweet spot.

Best Modes for Carrying Out Invention.

25 The presently preferred best modes for carrying out the present invention are illustrated by way of example in Figs. 1 to 4.

Referring to Fig. 1, shown is a first preferred embodiment of a contact lens CL according to the present invention. The contact lens CL is divided into a
30 central circular region and four concentric ring shaped regions. The central region 10 will be referred to as zone 1, the accommodation zone, or the sweet spot. The immediately adjacent first ring shaped region 20 will be referred to as zone 2. The second ring shaped region 30 immediately adjacent to zone 2 will be referred to as zone 3. The third ring shaped region 40 immediately adjacent to zone 3 will be referred to as zone 4.

1 The maximum diameter of a human pupil when it
is fully dilated is approximately 8 millimeters, so that
the ring shaped region 50 of the contact lens extending
radially outwardly from zone 4 is not an optical
5 surface, but merely functions as a carrier to maintain
the optical surface of zones 1 through 4 in position.

Structurally, the zones can be described as
follows. Zone 1 is preferably approximately 1.5 to 1.9
millimeters in diameter. Zone 2 and zone 3 are both
10 preferably approximately .5 millimeters in width. Zone
4 preferably extends outwardly from a radius of
approximately 2.5 millimeters to approximately 2.9
millimeters to approximately 8 millimeters. Thus, the
lens can be described as having a central sweet spot
15 (zone 1), two .5 millimeter intermediate zones (zones 2
and 3), and a distance zone (zone 4) extending outwardly
from the intermediate zones to the edge of the optical
portion of the contact lens (approximately 8 millimeters
radially outwards from the center). The total diameter
20 of the contact lens CL will be approximately 13 to
approximately 16 millimeters for a soft contact lens, so
that the carrier 50 will normally extend from
approximately 8 millimeters outwards to approximately
13.5 millimeters to approximately 15.0 millimeters, and
25 optimally 14.5 millimeters.

If this invention is practiced in connection
with a hard contact or RGP lens, the total diameter of
the contact lens CL would be between approximately 7.0
millimeters and approximately 11.0 millimeters, and
30 typically between approximately 8.0 millimeters and
approximately 10.5 millimeters, and optimally
approximately 9.5 millimeters.

Zone 1, the sweet spot, is preferably
spherical, although it can be aspherical. Zones 2, 3
35 and 4 are preferably aspherical in order to accommodate
transitions in corrective power across these zones.

1 Conventional contact lenses consist of a
carrier with a central lens portion. The central lens
portion is usually corrected for distance vision. This
is described in U.S. Patent 4, 119, 2312, Evans, which
5 is hereby incorporated by reference.

The present invention differs from conventional
multifocal contact lenses in that a small central
portion of the lens is overcorrected beyond the
correction that would be necessary for reading. This
10 central portion, the sweet spot or accommodation zone,
is small enough so that, surprisingly, it does not
impair distance vision when the user is looking at
distant objects, but it restores the ability to focus on
near objects within a substantial range of distances
15 from the wearer, such as, between 8 inches and 15
inches. It is believed that the transition zones
restore the ability to focus as follows: zone 2
restores the intermediate visual acuity between
approximately 15 inches and approximately 36 inches, and
20 zone 3 restores the intermediate visual acuity between
approximately 36 inches and full distance correction
(infinity).

In determining the appropriate curvatures for
the various zones in the contact lens CL, the correction
25 to restore distance vision must be determined first.
The distance power correction is then applied to zone 4.
The distance power correction is usually within a range
between +20.00 diopters to -20.00 diopters.

After the distance correction is determined,
30 the amount of correction for near vision ("add power")
should be calculated. A person with early to moderate
presbyopia would be prescribed a low additional reading
power of up to +1.75 diopters (referred to as a "low
add"). A moderate to advanced presbyope would require a
35 reading correction from 1.75 to 2.75 diopters (referred
to as a "high add").

1 For a high add presbyope, the aggregate change
in powers across the various zones is preferably
approximately 3.7 diopters. For a low add presbyope,
the aggregate change in powers across the various zones
5 is preferably approximately 2.6 diopters (approximately
70% of the total diopter shift for a high add).

The corrective power of the various zones
preferably does not remain constant within each zone.
Instead, for a high add presbyope, it is preferred that
10 there be as 1.6 diopter shift across zone 2, a 1.2
diopter shift across zone 3 and a .9 diopter shift
across zone 4, so that the total diopter shift across
zones 2, 3, and 4 is 3.7 diopters.

Because the sweet spot is so small, and because
15 it must be centered in the pupil in order for the
invention to function properly, the contact lens CL must
be precisely manufactured in order to be sure the sweet
spot is properly centered over the center of the pupil.
In order to accomplish this critical centering, it is
20 preferred to mark a 1.9 millimeter centered spot,
preferably white, on a pair of trial diagnostic contact
lenses. With such a pair of trial diagnostic contact
lenses, it is possible to detect whether a user's pupil
is off center (and other problems), so that the contact
25 lens of the present invention can be properly
manufactured to center the sweet spot over the pupil.

The inventor has discovered that an
overcorrected central portion of between approximately 1
to approximately 2.5 millimeters, and preferably
30 approximately 1.5 to approximately 1.9 millimeters
(optimally either 1.5 millimeters or 1.9 millimeters) in
diameter does not substantially impair distance vision
of a contact lens. Surprisingly, the inventor also has
discovered that overcorrecting the central portion
35 beyond the correction needed for near vision, restores
an unexpectedly large portion of the function of natural

1 accommodation of the eye so that focus can be achieved
over a range of near distances.

Although, other contact lenses are known with
central areas that are differently corrected than
5 distance portions, those central segments are either
larger than the present invention's "sweet spot," or
they do not overcorrect the sweet spot, or both.

It is preferred that the various zones have
constant widths even if the size of the sweet spot
10 differs. Thus, if the sweet spot is 1.9 millimeters in
diameter, the diameters of zones 2, 3, and 4 would all
be approximately .4 millimeters greater than the
corresponding diameters in a lens with a 1.5 millimeter
diameter sweet spot. It is also preferred that the
15 diopter shifts between zones 2, 3, and 4 remain constant
regardless of the size of the sweet spot for
mature presbyopes. Fig. 2 shows a contact lens
according to the present invention with a smaller sweet
spot.

20 For early presbyopia, the amounts of the
diopter shifts across zones 2, 3, and 4 are preferably
approximately 70% of the diopter shifts for mature
presbyopes. Thus, the preferred aggregate diopter shift
for early presbyopes is approximately 70% of the diopter
25 shifts for mature presbyopes. Thus, the aggregate
diopter shift across zones 2, 3, and 4 would be
approximately 2.6 diopters; the diopter shift across
zone 2 will be approximately 1.1 diopters; the diopter
shift across zone 3 would be approximately .8 diopters
30 and the diopter shift across zone 4 would be
approximately .6 diopters. Figs. 3 and 4 show contact
lenses for early presbyopes with large and small sweet
spots.

Although it is presently preferred to have
35 intermediate zone 2 and 3, it is not known whether the
presence of such zones is critical to the invention.
Further, it is not known whether the manner in which the

1 diopter shift is achieved by the aspheric shape of the
various zones is critical. At present, it is preferred
that the diopter shift take place at a constant radial
rate in each zone, so that there is a different constant
5 diopter shift rate in each of zones 2, 3, and 4.
However, it is also possible that the benefits of this
invention may be achievable by using varying diopter
shift rates within a zone, or to increase or decrease
the number of zones.

10 Further, it is not believed to be critical that
the diopter shifts be effected by shaping the contact
lens. For example, it is possible to achieve the
diopter shift by using material with differing indices
of refraction in various different portions of the lens.
15 Indeed, with appropriate control over the diffusion of
materials with different indices of refraction during
molding of contact lenses, it is possible that the
present invention could be practiced with a lens that is
spherical or that does not have differently formed lens
20 portions.

The sweet spot is preferably overcorrected
between 25% and approximately 100% stronger than the
prescribed reading correction requirement.

For example, for a high add, it would be
25 preferred that the sweet spot be from 3.5 to 5 diopters
more plus add power than the distance zone (zone 4),
between 3.5 to approximately 3.9 diopters being even
more preferred, and approximately 3.7 diopters being
optimal. For a low add, it would be preferred that the
30 sweet spot be from 2.0 to 3.5 diopters more plus add
power than the distance zone (zone 4), with between
approximately 2.4 and approximately 2.8 diopters being
more preferred, and optimally approximately 2.6
diopters.

35

1

EXAMPLE 1

A Microturn 9000 three axis radius lathe with aspheric surface cutting capabilities has been used to make contact lenses according to the present invention with base curves of 8.6 millimeters wet (6.6 millimeters dry). The lenses were manufactured dry from Ocufilecon B (a 53% water content material) and were hydrated afterwards. Therefore compensating calculations were made to achieve the appropriate hydrated parameters, such as base curve, radial expansion, linear expansion, power changes due to changes in index of refraction caused by hydration. When hydrating Ocufilecon B, the linear expansion parameter is approximately 1.35, the radial expansion parameter is approximately 1.30, and the power change parameter is approximately .57. The settings for the various radii of curvature in the various zones (for dry manufacturing using Ocufilecon B) are shown in the following cutting charts:

20

8.60 high add minus power

25

| | Zone 1 | 2 | 3 | 4 | DIA. | C.T. | DIST. |
|----------|--------|------|------|------|------|------|-------|
| CENTER | 1.10 | 1.50 | 1.90 | 6.00 | DIA. | C.T. | DIST. |
| POWER | 1.40 | 1.80 | 2.20 | 6.00 | DIA. | C.T. | POWER |
| pl | 6.73 | 6.98 | 7.17 | 7.30 | | .16 | |
| -.25 | 6.77 | 7.02 | 7.21 | 7.35 | | .16 | |
| -.50 | 6.83 | 7.06 | 7.25 | 7.40 | | .16 | |
| -.75 | 6.86 | 7.11 | 7.29 | 7.46 | | .16 | |
| 30 -1.00 | 6.90 | 7.15 | 7.33 | 7.50 | | .16 | |
| -1.25 | 6.93 | 7.18 | 7.37 | 7.53 | | .16 | |
| -1.50 | 6.96 | 7.22 | 7.41 | 7.58 | | .16 | |
| -1.75 | 7.00 | 7.25 | 7.45 | 7.62 | | .16 | |
| -2.00 | 7.05 | 7.29 | 7.49 | 7.66 | | .15 | |
| 35 -2.25 | 7.09 | 7.33 | 7.53 | 7.70 | | .15 | |
| -2.50 | 7.13 | 7.37 | 7.58 | 7.75 | | .15 | |
| -2.75 | 7.17 | 7.41 | 4.62 | 7.79 | | .15 | |

| | | | | | | |
|---|-------|------|------|------|------|-----|
| 1 | -3.00 | 7.21 | 7.46 | 7.67 | 7.84 | .14 |
| | -3.25 | 7.24 | 7.51 | 7.71 | 7.89 | .14 |
| | -3.50 | 7.28 | 7.56 | 7.76 | 7.94 | .14 |
| | -3.75 | 7.31 | 7.60 | 7.80 | 7.99 | .14 |
| 5 | -4.00 | 7.35 | 7.65 | 7.85 | 8.04 | .13 |
| | -4.25 | 7.38 | 7.70 | 7.90 | 8.07 | .13 |

8.60 high add plus power

10

| | Zone 1 | 2 | 3 | 4 | DIA. | C.T. | DIST. |
|--------|--------|------|------|------|------|------|-------|
| CENTER | 1.10 | 1.50 | 1.90 | 6.00 | DIA. | C.T. | POWER |
| POWER | 1.40 | 1.80 | 2.20 | 6.00 | DIA. | C.T. | POWER |

| | | | | | | |
|----|-------|------|------|------|------|-----|
| | p1 | 6.73 | 6.98 | 7.17 | 7.30 | .16 |
| 15 | +.25 | 6.71 | 6.95 | 7.13 | 7.27 | .17 |
| | +.50 | 6.68 | 6.91 | 7.09 | 7.23 | .17 |
| | +.75 | 6.65 | 6.87 | 7.05 | 7.19 | .17 |
| | +1.00 | 6.62 | 6.84 | 7.02 | 7.16 | .17 |
| | +1.25 | 6.59 | 6.80 | 6.98 | 7.12 | .17 |
| 20 | +1.50 | 6.56 | 6.77 | 6.94 | 7.08 | .17 |
| | +1.75 | 6.52 | 6.73 | 6.90 | 7.04 | .18 |
| | +2.00 | 6.49 | 6.70 | 6.87 | 7.00 | .18 |
| | +2.25 | 6.46 | 6.66 | 6.83 | 6.96 | .18 |
| | +2.50 | 6.44 | 6.63 | 6.80 | 6.93 | .18 |
| 25 | +2.75 | 6.40 | 6.59 | 6.76 | 6.89 | .18 |
| | +3.00 | 6.37 | 6.56 | 6.72 | 6.85 | .19 |
| | +3.25 | 6.34 | 6.53 | 6.69 | 6.80 | .19 |
| | +3.50 | 6.31 | 6.50 | 6.66 | 6.75 | .19 |
| | +3.75 | 6.28 | 6.47 | 6.62 | 6.73 | .20 |
| 30 | +4.00 | 6.26 | 6.44 | 6.59 | 6.70 | .20 |
| | +4.25 | 6.23 | 6.41 | 6.56 | 6.67 | .20 |

8.60 low add plus power

35

| | Zone 1 | 2 | 3 | 4 | DIA. | C.T. | DIST. |
|--------|--------|------|------|------|------|------|-------|
| CENTER | 1.10 | 1.50 | 1.90 | 6.00 | DIA. | C.T. | POWER |
| POWER | 1.40 | 1.80 | 2.20 | 6.00 | DIA. | C.T. | POWER |

| | | | | | | |
|----|-------|------|------|------|------|-----|
| 1 | p1 | 6.73 | 6.93 | 7.06 | 7.17 | .16 |
| | +.25 | 6.70 | 6.89 | 7.02 | 7.13 | .17 |
| | +.50 | 6.67 | 6.85 | 6.98 | 7.10 | .17 |
| | +.75 | 6.63 | 6.82 | 6.93 | 7.06 | .17 |
| 5 | +1.00 | 6.60 | 6.79 | 6.89 | 7.02 | .17 |
| | +1.25 | 6.58 | 6.74 | 6.86 | 6.98 | .17 |
| | +1.50 | 6.56 | 6.70 | 6.84 | 6.95 | .17 |
| | +1.75 | 6.52 | 6.67 | 6.80 | 6.91 | .17 |
| | +2.00 | 6.49 | 6.64 | 6.77 | 6.87 | .18 |
| 10 | +2.25 | 6.46 | 6.61 | 6.73 | 6.83 | .18 |
| | +2.50 | 6.43 | 6.58 | 6.70 | 6.79 | .18 |
| | +2.75 | 6.40 | 6.55 | 6.66 | 6.75 | .18 |
| | +3.00 | 6.37 | 6.52 | 6.63 | 6.72 | .19 |
| | +3.25 | 6.34 | 6.48 | 6.60 | 6.68 | .19 |
| 15 | +3.50 | 6.31 | 6.45 | 6.57 | 6.65 | .20 |
| | +3.75 | 6.28 | 6.42 | 6.54 | 6.62 | .20 |
| | +4.00 | 6.26 | 6.39 | 6.51 | 6.59 | .20 |
| | +4.25 | 6.23 | 6.36 | 6.47 | 6.56 | .20 |

20

8.60 low add minus power

| | | Zone 1 | 2 | 3 | 4 | | | |
|----|--------|--------|------|------|------|------|------|-------|
| | CENTER | 1.10 | 1.50 | 1.90 | 6.00 | DIA. | C.T. | DIST. |
| | POWER | 1.40 | 1.80 | 2.20 | 6.00 | DIA. | C.T. | POWER |
| 25 | | | | | | | | |
| | p1 | 6.73 | 6.93 | 7.06 | 7.17 | | | .16 |
| | -.25 | 6.77 | 6.96 | 7.10 | 7.21 | | | .16 |
| | -.50 | 6.81 | 7.00 | 7.14 | 7.25 | | | .16 |
| | -.75 | 6.85 | 7.03 | 7.18 | 7.29 | | | .16 |
| 30 | -1.00 | 6.89 | 7.07 | 7.22 | 7.33 | | | .16 |
| | -1.25 | 6.93 | 7.11 | 7.25 | 7.37 | | | .16 |
| | -1.50 | 6.97 | 7.15 | 7.29 | 7.41 | | | .16 |
| | -1.75 | 7.01 | 7.19 | 7.33 | 7.45 | | | .16 |
| | -2.00 | 7.05 | 7.24 | 7.37 | 7.50 | | | .15 |
| 35 | -2.25 | 7.08 | 7.28 | 7.41 | 7.54 | | | .15 |
| | -2.50 | 7.12 | 7.32 | 7.46 | 7.58 | | | .15 |
| | -2.75 | 7.16 | 7.36 | 7.51 | 7.62 | | | .15 |

| | | | | | | |
|---|-------|------|------|------|------|-----|
| 1 | -3.00 | 7.20 | 7.40 | 7.55 | 7.67 | .14 |
| | -3.25 | 7.23 | 7.44 | 7.59 | 7.71 | .14 |
| | -3.50 | 7.27 | 7.48 | 7.64 | 7.76 | .14 |
| | -3.75 | 7.31 | 7.52 | 7.68 | 7.80 | .14 |
| 5 | -4.00 | 7.35 | 7.57 | 7.73 | 7.85 | .13 |
| | -4.25 | 7.39 | 7.61 | 7.77 | 7.89 | .13 |

It is preferred that the contact lenses conform to industry standards for inside radii, which for soft contact lenses are presently between 7.5 and 9.5 millimeters, and typically between 8.30 millimeters and 8.6 millimeters. For RGP and hard lenses, the industry standard inside radii are between 7.0 millimeters and 8.5 millimeters, and typically between 7.3 and 8.2 millimeters.

It is presently preferred that the contact lens of the present invention comprise conventional soft contact lens material, such as Ocufilecon B with 53% water content, because contact lenses have been successfully manufactured using this material. However, any conventional soft or rigid contact lens material may be used to practice the invention (as long as appropriate compensations are made for parameters that may change during hydration for soft contact lens material). The inventor believes that Benz 55G or Methafilcon A may be as good as, or better than, Ocufilecon B in the practice of the present invention, but no lenses according to the present invention have yet been made with these materials.

While the present invention has been disclosed in connection with the presently preferred embodiments described herein, it should be understood that there may be other embodiments which fall within the spirit and scope of the invention as defined by the claims. For example, this invention can be practiced with contact lenses that are made by any method now known or

1 hereafter invented, including (but not limited to)
molding, spin casting, or extruding. This invention
also can be applied to intraocular lens implants and
refractive surgical procedures (including radial
5 keratotomy, photo refractive keratotomy, and corneal
implantation) that reshape the cornea. Furthermore,
this invention can be practiced in combination with
spherical or astigmatic (toric) contact lenses. Toric
lens prescriptions comprise spherical power corrections,
10 usually between +20 and -20 diopters (commonly between
+8 and -8 diopters), and cylindrical power corrections,
usually between .5 diopters and 10 diopters (commonly
between 1 and 4 diopters). The present invention can be
practiced within this entire range of toric (astigmatic)
15 lens prescriptions. Accordingly, no limitations are to
be implied or inferred in this invention except as
specifically and explicitly set forth in the claims.

Industrial applicability. This invention can
be used whenever it is desired to provide a contact lens
20 that corrects for distance vision as well as near and
intermediate vision.

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30

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CLAIMS

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What is claimed is:

1. A contact lens, comprising:

5

a circular central region overcorrected for near vision, wherein said central region is small enough to avoid impairing distance vision;

at least one ring shaped transition region extending radially outward from said central region;

10

a ring shaped outer region extending radially outward from said transition region corrected for distance vision; and

a ring shaped carrier region extending radially outward from said outer region;

15

wherein said transition region provides at least a partial diopter shift over said transition region between said overcorrection of said central region and said distance correction of said outer region.

20

2. A contact lens according to claim 1, wherein said central region is between approximately 1 millimeter and approximately 2.5 millimeters in diameter.

25

3. A contact lens according to claim 2, wherein said central region is between approximately 1.5 millimeters and approximately 1.9 millimeters.

4. A contact lens according to claim 1, wherein said central region has a diameter of less than approximately 1.9 millimeters.

30

5. A contact lens according to claim 2, wherein said central region has a diameter of approximately 1.5 millimeters.

6. A contact lens according to claim 2, wherein said central region has a diameter of approximately 1.9 millimeters.

35

7. A contact lens according to claim 1, wherein said central region is overcorrected for near vision by approximately 25% to approximately 100%.

1 8. A contact lens according to claim 1, wherein
said lens has at least a first transition region and a
second transition region.

5 9. A contact lens according to claim 8, wherein
said lens has two transition regions and each of said
transition regions is approximately .5 millimeters wide.

10 10. A contact lens according to claim 8, wherein
said transition regions are aspherical.

10 11. A contact lens according to claim 8, wherein
said transition regions are spherical.

15 12. A contact lens according to claim 8, wherein
said diopter shift across said first transition region
is at a first constant radial rate and said diopter
shift across said second transition region is at a
second constant radial rate.

20 13. A contact lens according to claim 8, wherein
said first transition region provides a diopter shift of
approximately 1.6 diopters, said second transition
region provides a diopter shift of approximately 1.2
diopters, and said outer region provides a diopter shift
of approximately .9 diopters.

25 14. A contact lens according to claim 8, wherein
said first transition region provides a diopter shift of
approximately 1.1 diopters, said second transition
region provides a diopter shift of approximately .8
diopters, and said outer region provides a diopter shift
of approximately .6 diopters.

30 15. A contact lens according to claim 1, wherein
said outer region has a diameter of approximately 8
millimeters.

35 16. A contact lens according to claim 1 wherein
optical correction of at least one of said regions is
provided by a material with differing indices of
refraction in different portions.

35 17. A contact lens according to claim 1, wherein
said lens is made from materials selected from the group
consisting of conventional soft lens material, rigid gas

1 permeable contact lens material, or hard contact lens material.

18. An intraocular implant, comprising:

5 a circular central region overcorrected for near vision, wherein said central region is small enough to avoid impairing distance vision;

at least one ring shaped transition region extending radially outward from said central region;

10 a ring shaped outer region extending radially outward from said transition region corrected for distance vision; and

a carrier region extending radially outward from said outer region;

15 wherein said transition region provides at least a partial diopter shift over said transition region between said overcorrection of said central region and said distance correction of said outer region.

19. A refractive surgical procedure, comprising: shaping a human cornea to provide:

20 a circular central region overcorrected for near vision, wherein said central region is small enough to avoid impairing distance vision;

at least one ring shaped transition region extending radially outward from said central region;

25 a ring shaped outer region extending radially outward from said transition region corrected for distance vision;

30 wherein said transition region provides at least a partial diopter shift over said transition region between said overcorrection of said central region and said distance correction of said outer region.

20. A contact lens having a pupil area, comprising:

35 a central accommodation zone covering approximately half of said pupil area overcorrected for near vision by between approximately 25% to approximately 100%;

1 at least one concentric transition region extending
radially outward from said accommodation region; and
a concentric outer region extending radially outward
from said transition region corrected for distance
5 vision;

wherein said transition region provides at least a
partial diopter shift over said transition region
between said overcorrection of said central
accommodation zone and said distance correction of said
10 outer region.

21. A contact lens according to claim 20, having an
add power of between approximately 3.5 and approximately
3.9 diopters.

22. A contact lens according to claim 20, having an
15 add power of approximately 3.7 diopters.

23. A contact lens according to claim 20, having an
add power of between approximately 2 and approximately
3.5 diopters.

24. A contact lens according to claim 20, having an
20 add power of between approximately 2.4 and 2.8 diopters.

25. A contact lens according to claim 20, having an
add power of approximately 2.6 diopters.

26. A process for aligning a central region of a
contact lens, comprising:
25 marking a centered spot on a diagnostic contact
lens; and

detecting whether a user's pupils would be aligned
with said central region.

27. A process according to claim 26, wherein said
30 spot has a diameter of approximately 1.9 millimeters.

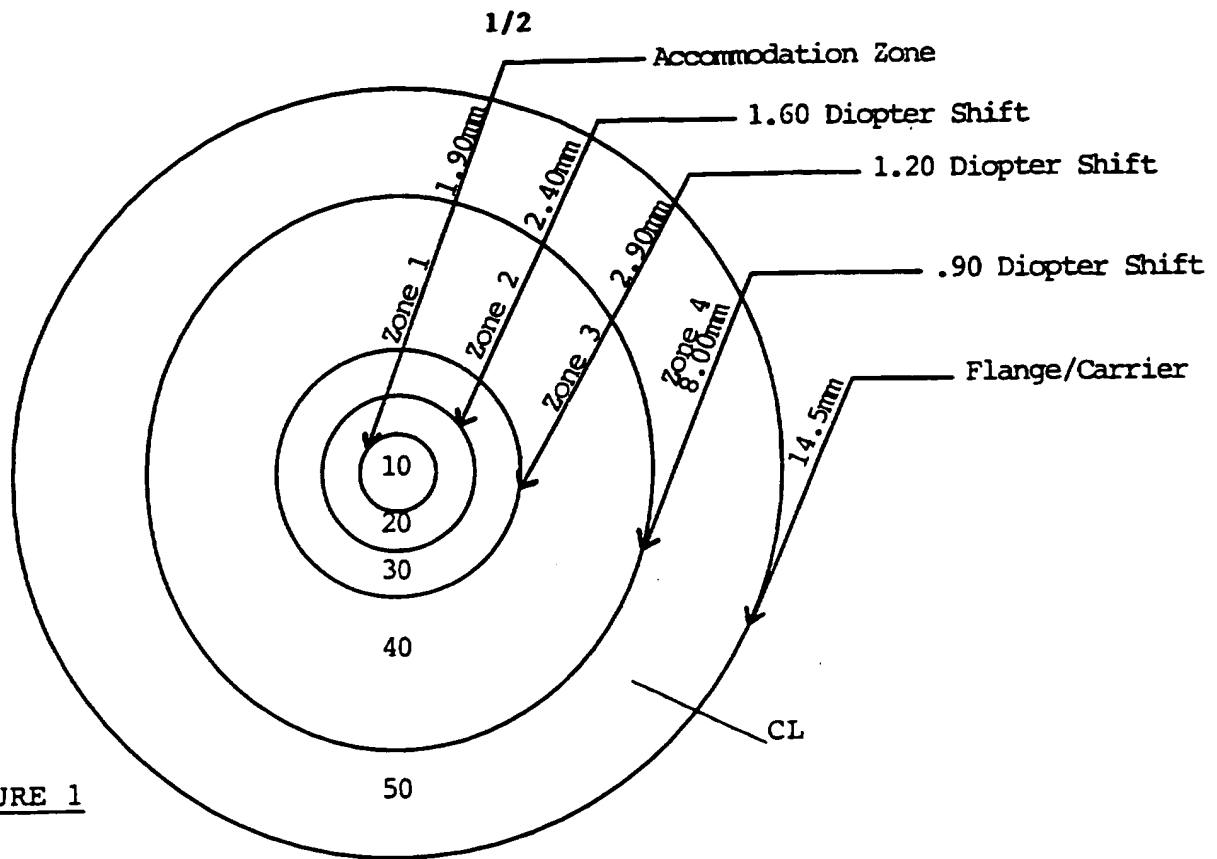


FIGURE 1

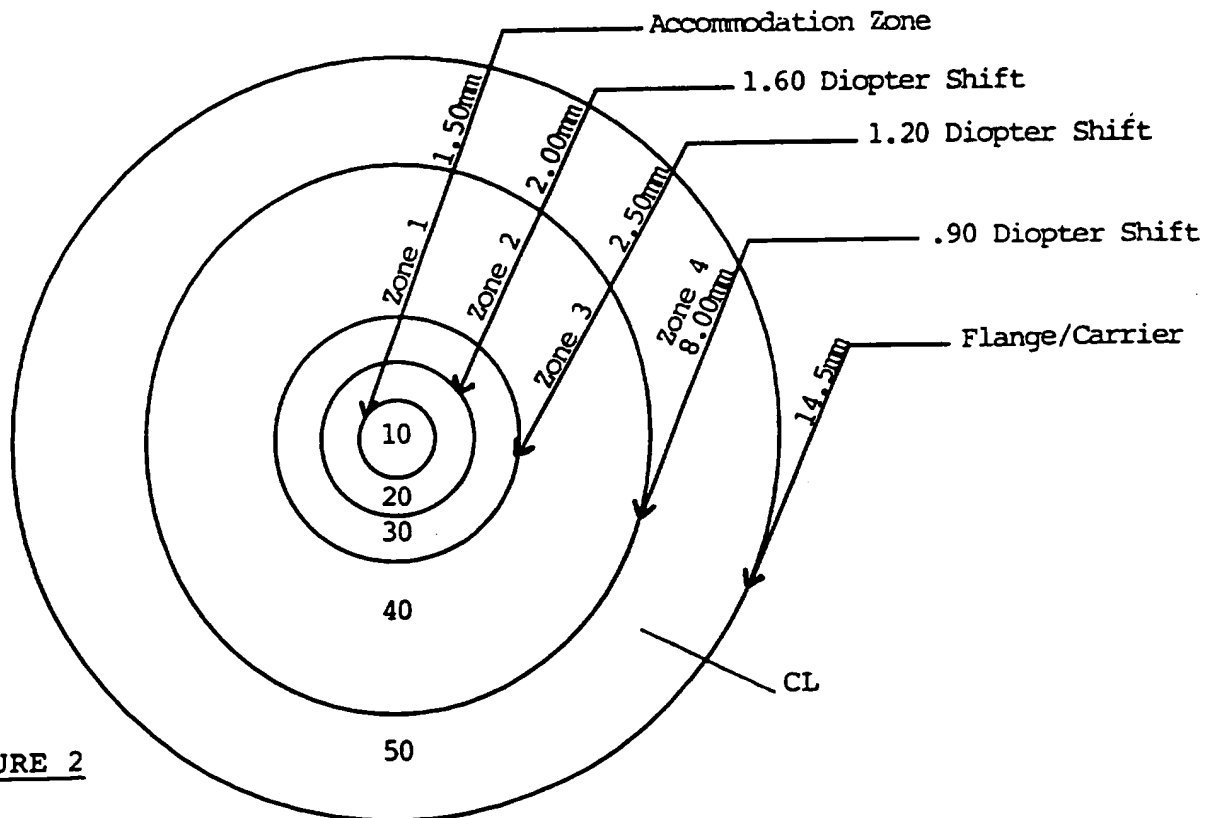
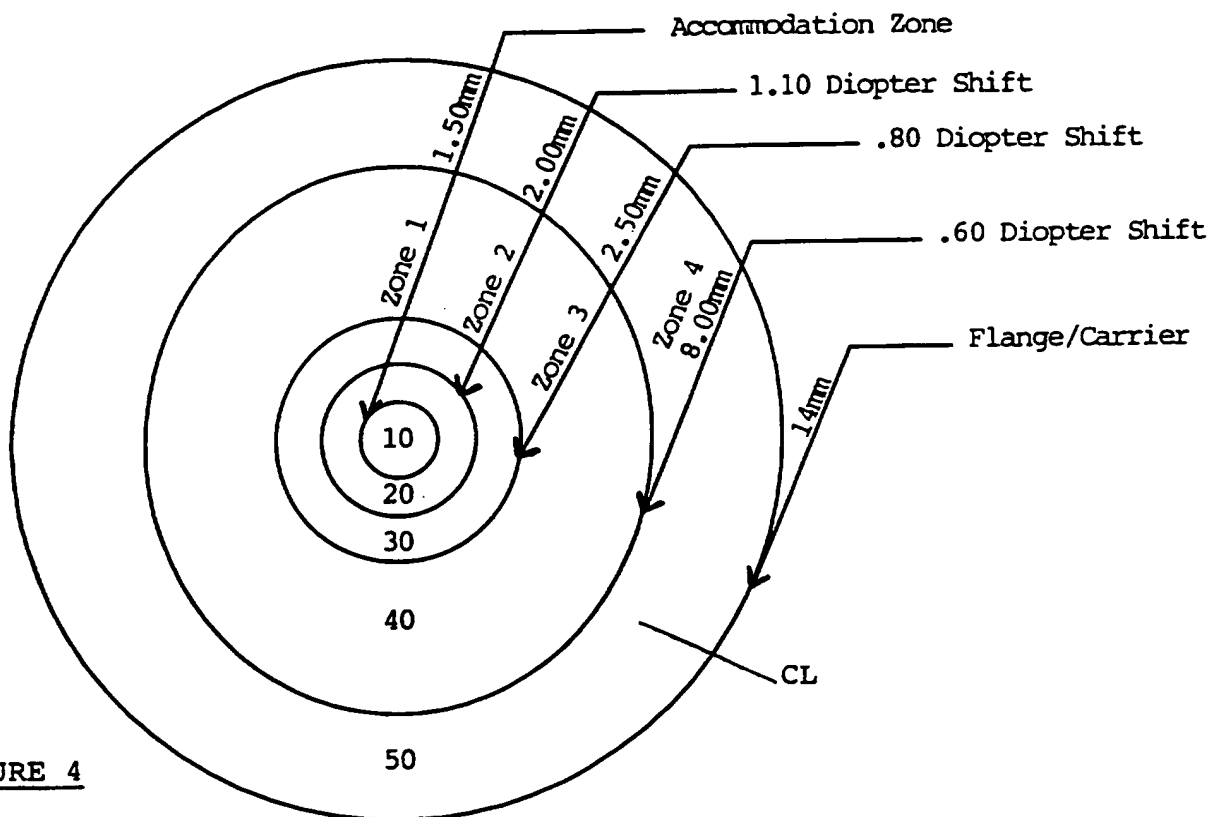
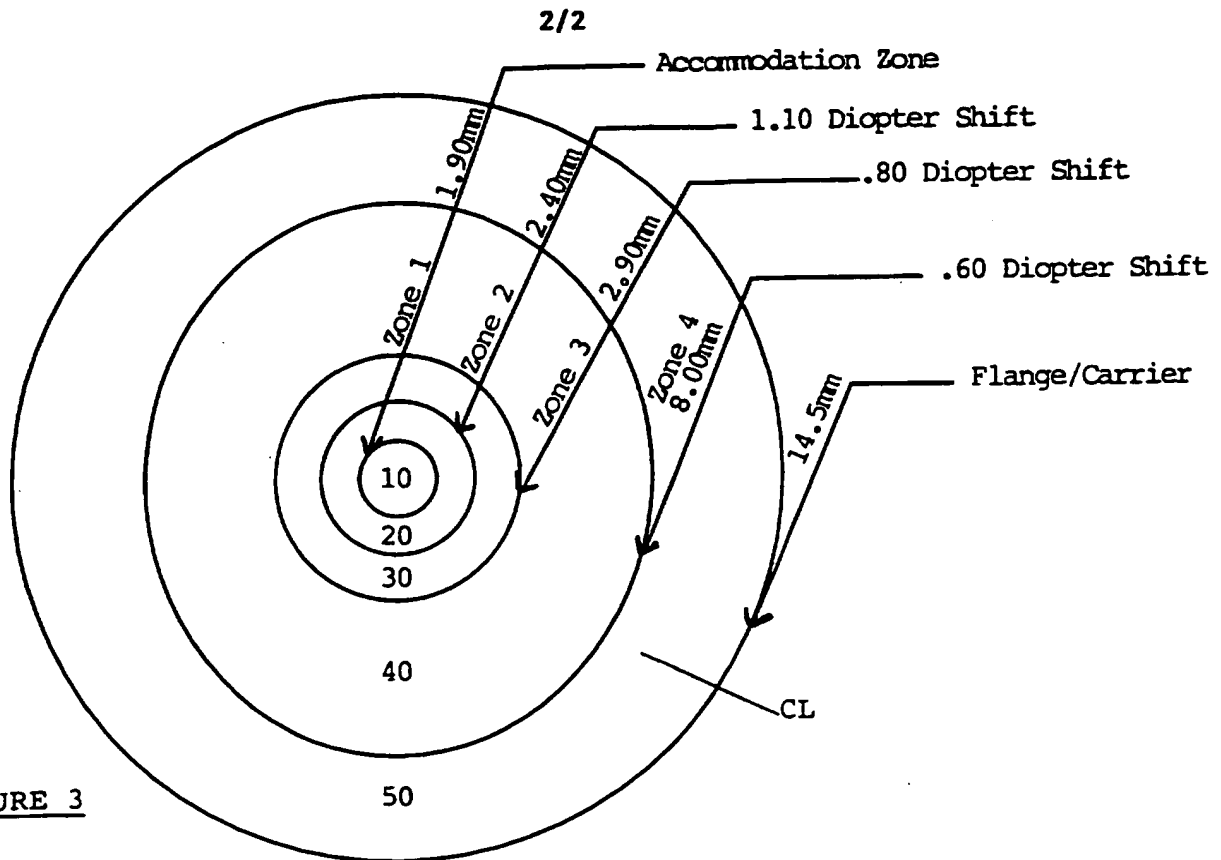


FIGURE 2



INTERNATIONAL SEARCH REPORT

International application No.
PCT/US96/15589

A. CLASSIFICATION OF SUBJECT MATTER

IPC(6) : G02C 7/02, 7/04; A61F 2/16; A61M 1/00
US CL : 351/161, 177; 623/6; 604/28
According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

U.S. : 351/161, 177; 623/6; 604/28

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)

APS

C. DOCUMENTS CONSIDERED TO BE RELEVANT

| Category* | Citation of document, with indication, where appropriate, of the relevant passages | Relevant to claim No. |
|-----------|---|-----------------------|
| X | US 5,406,341 A (BLUM et al) 11 April 1995, Abstract, Figure 1 | 26-27 |
| A | US 4,869,587 A (BREGER) 26 September 1989, column 9, lines 25-62, column 4, lines 51-56, Figures 5-7. | 1-17, 20-25 |
| A | US 5,158,572 A (NIELSON) 27 October 1992, column 2, line 42 to column 3, line 62, Figure 7. | 1-25 |

☐ Further documents are listed in the continuation of Box C.

☐ See patent family annex.

* Special categories of cited documents:

A document defining the general state of the art which is not considered to be of particular relevance

E earlier document published on or after the international filing date

L document which may throw doubt on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)

O document referring to an oral disclosure, use, exhibition or other means

P document published prior to the international filing date but later than the priority date claimed

T later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention

X document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone

Y document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art

Z document member of the same patent family

Date of the actual completion of the international search

30 DECEMBER 1996

Date of mailing of the international search report

31 JAN 1997

Name and mailing address of the ISA/US
Commissioner of Patents and Trademarks
Box PCT
Washington, D.C. 20231

Authorized officer

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Telephone No. (703) 308-0956

Box I Observations where certain claims were found unsearchable (Continuation of item 1 of first sheet)

This international report has not been established in respect of certain claims under Article 17(2)(a) for the following reasons:

1. ☐ Claims Nos.:
because they relate to subject matter not required to be searched by this Authority, namely:
2. ☐ Claims Nos.:
because they relate to parts of the international application that do not comply with the prescribed requirements to such an extent that no meaningful international search can be carried out, specifically:
3. ☐ Claims Nos.:
because they are dependent claims and are not drafted in accordance with the second and third sentences of Rule 6.4(a).

Box II Observations where unity of invention is lacking (Continuation of item 2 of first sheet)

This International Searching Authority found multiple inventions in this international application, as follows:

Please See Extra Sheet.

1. ☒ As all required additional search fees were timely paid by the applicant, this international search report covers all searchable claims.
2. ☐ As all searchable claims could be searched without effort justifying an additional fee, this Authority did not invite payment of any additional fee.
3. ☐ As only some of the required additional search fees were timely paid by the applicant, this international search report covers only those claims for which fees were paid, specifically claims Nos.:
4. ☐ No required additional search fees were timely paid by the applicant. Consequently, this international search report is restricted to the invention first mentioned in the claims; it is covered by claims Nos.:

Remark on Protest

- ☐ The additional search fees were accompanied by the applicant's protest.
- ☒ No protest accompanied the payment of additional search fees.

BOX II. OBSERVATIONS WHERE UNITY OF INVENTION WAS LACKING

This ISA found multiple inventions as follows:

Group I, claim(s) 1-18 and 20-25, drawn to a lens providing multifocal optical correction (351/161;623/6).

Group II, claim(s) 19, drawn to a surgical procedure for reshaping the cornea (604/28).

Group III, claim(s) 26-27, drawn to a process for aligning the central region of a contact lens (351/177).

The inventions listed as Groups I, II and III do not relate to a single inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons: the special technical feature of the Group I invention is a lens providing optical correction; the special technical feature of the Group II invention is a surgical procedure for reshaping a human cornea; while the special technical feature of the Group III invention is a means of aligning a contact lens. Since the special technical feature of the Group I invention is not present in the Groups II and III claims, the special technical feature of the Group II invention is not present in the Groups I and III claims, and the special technical feature of the Group III invention is not present in the Groups I and II claims, unity is lacking.